AUG 1 6 2001

K011069

6.0 510(k) Summary of Safety and Effectiveness Information:

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A) Submitter Information:

Submitter's Name:	Lucinda L. Fox
Address:	Davol Inc. 100 Sockanossett Crossroad Cranston, Rhode Island 02920
Phone Number:	(401) 463-7000
Fax Number:	(401) 463-3845
Contact Person:	Lucinda L. Fox
Date of preparation:	March 15, 2001

B) Device Name:

Trade Name:	Davol® AquaSens™ Fluid Monitoring System
Common/Usual Name:	Insufflator, Hysteroscopic, Fluid Monitoring Accessory
Classification Name:	Hysteroscopic Insufflator, Accessory

C) Predicate Product:

AquiSens Fluid Monitoring System (K953583)

With the exception of limits on the intended use, the Davol® AquaSens™ Fluid Monitoring System (Proposed Product) described in this submission

will be identical to the product Davol currently distributes. The distributed product is covered by a premarket notification submitted by Aquintel, Inc. (Aquintel), 912 Second Street, Bethoud, Colorado 80513. The Aquintel submission, K952583, received concurrence on August 24, 1995. With the exception of minor modifications, the Proposed Product is substantially equivalent to the product described in Aquintel's submission (Predicate Product) (see Exhibit 3). The key difference between the Predicate Product and the Proposed Product is a mounting bar designed to hold Davol's HydroFlex™ Reusable Controller (Controller). The mounting bar was added as a user convenience and serves no other function except to hold the Controller. The product that Davol currently markets includes the mounting bar.

C) Description and Intended Use:

The Davol® AquaSens™ Fluid Monitoring System is intended for use in gynecological surgical and diagnostic procedures. The system consolidates the supply and collection of irrigation fluids used during hysteroscopic procedures to distend the uterus and to clear the operative site of blood and debris. The system monitors irrigation fluid losses and indicates when such losses exceed a level pre-set by the surgeon.

The Proposed Product will automatically monitor irrigation fluid loss during hysteroscopic procedures by measuring the total weight of the irrigation bag(s), tubing, and waste canisters. The system includes a column/I.V. Pole that rests on a scale, which is located in the Wheeled Base at the bottom of the I.V. Pole. At the beginning of a procedure, the scale is zeroed to reflect the total weight of the column with irrigation fluids and collection canisters loaded. A force transducer, the Load Cell, measures the total fluid weight of the column (includes input and output fluid). The Load Cell is connected to a battery powered Fluid Monitor Electronic Unit,

where the information is displayed as "Fluid Loss" or "Total System Volume."

The Proposed Product is a physical measurement device designed to detect loss of fluid weight. Non-sterile/non-invasive, the system does not attempt to detect or treat disease, nor is it designed for any other therapeutic purpose. Its sole function is to identify discrepancies between fluid input and output by tracking changes in total system fluid weight, then converting the information for display as volume lost/gained. The fluid weight is converted to volume assuming a specific gravity of one gram per milliliter (mL).

Total system fluid volume is defined as all irrigation fluid loaded on the I.V. Pole at the top of the column and all fluid collected in the suction canisters located at the bottom of the column. Changes in total system fluid volume are displayed on the Fluid Monitor Electronic Unit in milliliters. A decrease in system fluid volume is shown on the digital display as a negative number and a gain is shown as a positive number. When used as recommended, the collection canisters will not allow used fluid to reenter the patient.

A) Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

A comparison chart is provided summarizing the similarities and differences in intended use, design, and performance between the Predicate and Proposed Products (reference Attachment 1 to this Section). The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree was utilized to make a determination of substantial equivalence.

1) **Does the New Device Have the Same Indication Statement.**

No. Both the Proposed and Predicate Products are intended for use in gynecological surgical and diagnostic procedures. Both systems consolidate the supply and collection of irrigation fluids used during hysteroscopic procedures to distend the uterus and to clear the operative site of blood and debris. Both systems monitor irrigation fluid loss and indicate when such loss exceeds a level pre-set by the user. However, the Proposed Product will be limited to gynecological surgical and diagnostic procedures. The use limitation was imposed by legal agreement, not technological changes between the Proposed and Predicate Products.

2) **Does the New Device have the same Technological Characteristics, e.g., Design, Materials, etc.?**

Yes. With the exception of minor modifications, both the Predicate and Proposed Products are identical in terms of technological characteristics. Both use a mechanical scale/electronic monitoring unit to track total fluid volume and calculate fluid loss/gain. Both allow the user to select the fluid loss alert level and both include visible/audible alarms to notify the user when the selected level is reached/exceeded. Both track and display fluid loss information on identical electronic units. The primary difference between the Proposed and Predicate Products is a mounting pole designed to hold Davol's **HydroFlex** Reusable Controller. The Instructions for Use reflect the addition of information covering the use of Davol's **HydroFlex** hysteroscopic products with the Proposed Product. It should be noted that the product Davol currently distributes includes the mounting pole and the **HydroFlex** product information.

3) **Are the descriptive characteristics precise enough to ensure equivalence?**

Yes. With the exception of minor modifications, both the Predicate and Proposed Products are identical in design, function, materials, and technology. Both use the same mechanical scale/electronic monitoring unit to track total fluid volume and calculate fluid loss/gain. Both are designed so the user can select the fluid loss alert level and both include visible/audible alarms to notify the user when the selected level is reached/exceeded. The primary difference between the Proposed and Predicate Products is a mounting pole designed to hold Davol's **HydroFlex** Reusable Controller and the urological indication. It should be noted that the product Davol currently distributes includes the mounting pole and the **HydroFlex** product information.

CONCLUSION:

Based upon the above information, the **Davol AquaSens** Fluid Monitoring System is substantially equivalent to the AquiSens Fluid Monitoring System. It should be noted that, except for the urological indication, the Proposed Product will be identical to the product Davol currently distributes.

Substantial Equivalence Table

Feature	Aquintel AquiSens Monitoring System	Davol AquaSens Fluid Monitoring System*
Indication for Use – Gynecological	Same	Same
Indication for Use – Urological	Yes	No**
Physical Measurement Device	Yes	Yes
Non-Sterile/Non-Invasive Device	Yes	Yes
Monitors irrigation fluid losses and indicates when such losses exceed pre-set level	Yes	Yes
Alert Level Set by User	Yes	Yes
Battery Powered Fluid Monitor Electronic Unit	Yes	Yes
HydroFlex Controller Mounting Pole	Yes[1]	Yes
Distention Fluid Hangers	Yes, 4	Yes, 4
Adjustable I.V. Pole	Yes	Yes
Suction Canisters Holders	Yes, 8	Yes, 8
Support Shelf Isolated from Load Cell	Yes	Yes
Load Cell	Yes	Yes
Wheeled Base	Yes	Yes
Visible Alarms	Yes	Yes
Audible Alarm	Yes	Yes
Digital Displays	Yes	Yes
Displays Total Volume/Fluid Loss	Yes	Yes
Fluid Loss Bar Graph Display	Yes	Yes
Fluid Alert Level	0 - 3000[2]	0 - 3000

[1] This feature was added after 510(k) concurrence and Aquintel determined it to be an insignificant change not affecting the safety or efficacy.

[2] The Fluid Alert Level was 0 – 1900 in K952583. This feature was changed after 510(k) concurrence and Aquintel determined it to be an insignificant change that did not affect the safety or efficacy.

* With the exception of the urological indication, it should be noted that the Proposed Product will be identical to the product Davol currently distributes .

** Use limitation was imposed by legal agreement, not technological changes between the Proposed and Predicate Products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2001

Davol, Inc., Sub. C.R. Bard, Inc.
% Mr. Robert Mosenkis
CITECH Medical Devices
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K011069
AquaSens™ Fluid Monitoring System
Dated: August 2, 2001
Received: August 3, 2001
Regulatory Class: II
21 CFR 884.1700/Procode: 85 HIG

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: Unknown

Device Name: Davol® AquaSens™ Fluid Monitoring System

Indications for Use:

The Davol® AquaSens™ Fluid Monitoring System is intended for use in gynecological surgical and diagnostic procedures. The system consolidates the supply and collection of irrigation fluids used during hysteroscopic procedures to distend the uterus and to clear the operative site of blood and debris. The system monitors irrigation fluid losses and indicates when such losses exceed a level pre-set by the surgeon.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Kessler

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011069

Prescription Use ✓ Or Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)